UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re SANOFI-AVENTIS SECURITIES LITIGATION

MEMORANDUM DECISION AND ORDER

07 cv 10279 (GBD)
08 cv 00021 (GBD)

GEORGE B. DANIELS, District Judge:

Plaintiffs City of Edinburgh Council on behalf of the Lothian Pension Fund, New England Carpenters Guaranteed Annuity Fund, the City of Taylor General Employees Retirement System on behalf of itself and all others similarly situated, and Carrie Smith, individually and on behalf of all others similarly situated (collectively, "Plaintiffs") brought this action against the French pharmaceutical company sanofi-aventis SA ("sanofi") and Individual Defendants Jean-Francois Dehecq, Gerard Le Fur, Hanspeter Spek, Marc Cluzel, Jean-Pierre Lehner, Douglas A. Greene, and Jean-Claude Leroy. Plaintiffs assert claims "[a]gainst [a]ll Defendants" for violation of Section 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b), and Rule 10b-5 thereunder, and for control party liability pursuant to Section 20(a) of the Exchange Act.

Plaintiffs moved pursuant to the Hague Convention[1] for the issuance of a Letter of Request directed to The Foreign and Commonwealth Office for the European Medicines Agency to produce documents and, if necessary, provide testimony.[2] See Docket # 66. Defendants'

[1] The Hague Convention on the Taking of Evidence Abroad in Civil or Commercial Matters, Mar. 18, 1970, 23 U.S.T. 2555, T.I.A.S. No. 7444.

[2] By letter, Plaintiffs revised the scope of their document requests after the motion was fully briefed and then invoked for the first time English Law, The Evidence (Proceedings in

move pursuant to Fed. R. Civ. P. 12(b)(6) and 9(b) to dismiss the First Amended Complaint in its entirety against all Defendants for failure to state a claim. The motion to dismiss is DENIED as to Defendants sanofi, Le Fur, and Spek. The motion to dismiss is GRANTED as to Defendants Dehecq, Cluzel, Lehner, Greene, and Leroy.

BACKGROUND

A. PARTIES

sanofi-aventis SA ("sanofi") is the third largest pharmaceutical company in the world. First Amended Complaint ("FAC") ¶ 20. Its depository shares and depository receipts trade on exchanges around the globe, including the New York Stock Exchange. The Individual Defendants are sanofi executives who were involved in the development of rimonabant as a commercially viable drug. FAC ¶¶ 21-26. Plaintiffs are purchasers of sanofi securities during the period of February 20, 2006, through June 13, 2007 (hereinafter, "Class Period"), who were allegedly damaged as a result of sanofi's and the individual defendant's violations of federal securities laws. FAC ¶ 2.

B. PROCEDURAL HISTORY

After initially filing separate lawsuits, Plaintiffs filed a Consolidated Complaint asserting section 10(b) and section 20(a) claims. See Docket # 20. This Court dismissed Plaintiffs' Consolidated Complaint on Defendants' motion. See In re Sanofi-Aventis Secs. Litig., 2009 U.S. Dist. LEXIS 88580 (S.D.N.Y. Sept. 25, 2009), available at Docket # 54; see also Docket # 23 (Defendants' Motion).

In the Memorandum Opinion and Order, this Court dismissed Plaintiffs' section 10(b)

Other Jurisdictions) Act of 1975. See Letter from Laurie L. Largent, Plaintiffs' counsel, to the Hon. George B. Daniels (November 23, 2010).

claim on the grounds that: (1) Plaintiff had failed to identify any actionable misstatements[3] or material omissions;[4] and (2) the Consolidated Complaint failed to adequately plead scienter.[5] This Court also dismissed the section 20(a) claim for failure to allege a primary violation under section 10(b). See id. at *22.

Plaintiffs subsequently moved for reconsideration to the extent of granting Plaintiffs leave to amend. See Docket # 56. This Court granted Plaintiffs' motion, having found that the

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[3] This Court considered three alleged misstatements. See id. at *11 (summarizing statements in Consolidated Complaint ("CC") ¶¶ 102, 109, 110); see also id. at *10 (noting that "Plaintiffs conceded that the majority of the allegedly misleading statements in the complaint were unactionable"). This Court concluded that the Consolidate Complaint "fail[ed] to set forth facts showing that [D]efendants misstated the frequency with which negative side effects occurred among the studies' subjects or misrepresented the test patients response to rimonabant vis-a-vis the patients receiving placebos." Id. at *14. Rather, "taken in context with the publicly available data," the alleged misstatements "amount[ed] to little more than expressions of opinion." Id.

[4] Plaintiffs identified Defendants' failure to disclose omitted safety data about rimonabant. This Court found that the alleged omission was not actionable because "Plaintiffs [did] not allege that [s]anofi falsified study data or that [D]efendants concealed clinical data gathered in the trials from either the investing public or the FDA." Id. at *16. The Court noted that Plaintiffs "failed to identify any specific safety data that was omitted from sanofi's public disclosures which defendants had an affirmative duty to disclose," id., having conceded at oral argument that "[D]efendants did not have an affirmative duty to disclose either the contents of the FDA's approvable letter or [s]anofi's response thereto." Id. at *16 n.3.

[5] This Court found that Plaintiffs' allegations failed to establish either a motive and opportunity to commit fraud or reckless. This Court reasoned that Plaintiffs proffered a generalized motive – namely, avoiding increased scrutiny and the existence of pipeline problems endemic in the pharmaceutical industry at large – that, even if sufficient, was rendered untenable by Plaintiff's allegations regarding the public dissemination of the clinical study data at issue. Id. at *18-20. This Court also reasoned that "[i]t was not reckless for defendants to interpret the drug's side effects to be either statistically insignificant or insufficiently severe to prevent FDA approvable." Id. at *21. Plaintiffs, the Court explained, could not "create an inference of fraud based on recklessness by simply alleging that [s]anofi 'might have been more cautious or concerned' about negative drug side effects or that they could have interpreted the clinical trial data in a more conservative fashion." Id.

proposed complaint "cures the fatal deficiencies in the Consolidated Complaint and adequately pleads violations of the federal securities laws." See Docket # 63. Plaintiffs subsequently filed the First Amended Complaint. See Docket # 64.

C. rimonabant

rimonabant is a compound that directly affects the brain's hunger signal by reducing the craving for food. FAC ¶ 4. In April 2005, sanofi filed a New Drug Application ("NDA") with the United States Food and Drug Administration ("FDA") to use and promote rimonabant as a treatment for obesity in the United States. FAC ¶ 3. On an unknown date, the FDA subsequently asked for information about suicidality[6] in the rimonabant clinical trials. FAC ¶ 6. Sanofi, also on an unknown date, produced records of several cases of suicidal ideation that had not been initially reported in the NDA in response. FAC ¶ 6. Plaintiffs allege that these records showed a "signal" of suicidality pursuant to the World Health Organization's definition of the term. FAC ¶ 6.

On February 17, 2006, the FDA sent sanofi a letter stating that "review of the preclinical and clinical data raised concern about associations between rimonabant and increased frequencies of psychiatric adverse events, including suicidality." FAC ¶ 7. The FDA directed sanofi to obtain a formal, independent assessment of the link between rimonabant and suicidality from Dr. Kelly Posner at Columbia University. FAC ¶¶ 7-8.

On October 26, 2006, sanofi submitted the results from Dr. Posner's study. FAC ¶ 10. Plaintiffs allege that "the assessment showed a definite link between rimonabant and suicidality,

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[6] "Suicidality" or "suicidal ideation" are terms of art that are used to categorize a range of suicidal thoughts from fleeting suicidal feelings to the planning of a suicide attempt. FAC ¶¶ 6 n.1, 7.

with many more patients taking rimonabant developing suicidality than patients taking placebo." FAC ¶ 10. Plaintiffs also allege that "the link between rimonabant and suicidality was statistically significant." FAC ¶ 10.

On June 13, 2007, the FDA held a meeting regarding the rimonabant application. FAC ¶ 16. The FDA disclosed the suicidality information that sanofi had submitted on October 26, 2006, stating that "[c]ompared to placebo, 20 mg rimonabant statistically significantly increased suicidality . . . ." FAC ¶ 16. The FDA Advisory Committee of experts unanimously recommended that the FDA deny sanofi's application for rimonabant. FAC ¶ 16. Sanofi withdrew its application before the FDA issued a final decision. FAC ¶ 18.

STANDARD OF REVIEW

A. 12(b)(6) STANDARD

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 129 S. Ct. 1937,1949 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). This standard is met "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. A court should not dismiss a complaint for failure to state a claim if the factual allegations sufficiently "raise a right to relief above the speculative level." Twombly, 550 U.S. at 555

The task of the court in ruling on a motion to dismiss is to "assess the legal feasibility of the complaint, not to assay the weight of the evidence which might be offered in support thereof." In re Initial Pub. Offering Sec. Litig., 383 F. Supp. 2d 566, 574 (S.D.N.Y. 2005) (internal quotation marks and citation omitted). The court must accept all well-pleaded factual

allegations in the complaint as true, and draw all reasonable inferences in the plaintiffs favor. Chambers v. Time Warner, Inc., 282 F.3d 147, 152 (2d Cir. 2002). In deciding a motion to dismiss, the Court is not limited to the face of the complaint. The court "may [also] consider any written instrument attached to the complaint, statements or documents incorporated into the complaint by reference, legally required public disclosure documents filed with the SEC, and documents possessed by or known to the plaintiff and upon which it relied in bringing the suit." ATSI Commc'ns v. Shaar Fund, Ltd., 493 F.3d 87, 98 (2d Cir. 2007).

In the context of securities fraud claims, a complaint must meet heightened pleading requirements. A plaintiff must "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent" pursuant to Fed. R. Civ. P. 9(b) and the Private Securities Litigation Reform Act of 1995 ("PSLRA"). Id. at 99; see also 15 U.S.C. § 78u-4(b)(1). The PSLRA also requires that "if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1).

B. SCOPE

This Court dismissed the Consolidated Complaint in its entirety after reviewing all of the factual allegations. This Court did not, as Plaintiffs contend, consider some of the alleged misstatements and omissions and preserve others. As reiterated at the Oral Argument on the instant motion, "the allegations in the consolidated complaint [were] totally insufficient" to sustain a Rule 10-b(5) claim. See Oral Argument Transcript (November 30, 2010), at 37. Accordingly, this Court will not entertain "debate . . . about the sufficiency of the allegations in

the consolidated complaint." Id.

Furthermore, this Court never addressed whether the misstatements or omissions alleged in the Consolidated Complaint were inherently insufficient as a matter of law. Contrary to Defendants' assertion, the mere fact that many of the factual allegations in the First Amended Complaint are verbatim or substantially similar to those in the Consolidated Complaint does not preclude Plaintiffs from having sufficiently pled a section 10(b) or section 20(a) claim. The issue on the instant motion is whether, in light of the differences, the factual allegations in the First Amended Complaint are "different and clearer and sufficient to overcome . . . the deficiencies."[7] Id. at 37-38.

SECTION 10(b) CLAIM

Section 10(b) makes it unlawful to "use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe." 15 U.S.C. § 78j(b). SEC Rule 10b-5, 17 C.F.R. § 240.10b-5(b), states that it "shall be unlawful for any person . . . [t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." To state a claim in a private action under section 10(b) and Rule 10b-5, a plaintiff must prove "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a

[7] To aid such an inquiry, this Court requested post-oral argument submissions from the parties. See Oral Argument Transcript (November 30, 2010), at 38-39. On December 3, 2010, Plaintiffs submitted a redline version of the First Amended Complaint identifying the new and amended allegations. On December 13, 2010, Defendants submitted a letter brief addressing why the allegations in the First Amended Complaint are not substantively different from the original Consolidate Complaint. On December 20, 2010, Plaintiffs submitted a response.

connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission [or transaction causation]; (5) economic loss; and (6) loss causation." Stoneridge Inv. Partners, L.L.C. v. Scientific-Atlanta, Inc., 552 U.S. 148, 157 (2008) (citing Dura Pharms., Inc. v. Broudo, 544 U.S. 336, 341-42 (2005)); Ganino v. Citizens Utils. Co., 228 F.3d 154, 161 (2d Cir. 2000). Here, Defendants dispute only the sufficiency of the FAC with respect to the first and second elements.

A. MATERIAL MISREPRESENTATION OR OMISSION

1. Legal Standard

An omission is actionable only if: (a) the omitted fact is material; and (b) the speaker had a duty to disclose the omitted fact. See Basic Inc. v. Levinson, 485 U.S. 224, 231-32 (1988); see also id. at 239 n.17 ("[s]ilence, absent a duty to disclose, is not misleading under Rule 10b-5."); Resnick v. Swartz, 303 F.3d 147, 154 (2d Cir. 2002) ("For an omission to be actionable, the securities laws must impose a duty to disclose the omitted information."); ZVI Trading Corp. Employees' Money Purchase Pension Plan & Trust v. Ross (In re Time Warner Inc. Sec. Litig.), 9 F.3d 259, 267 (2d Cir. 1993) ("[A]n omission is actionable under the securities laws only when the corporation is subject to a duty to disclose the omitted facts.").

The materiality of an omitted fact depends upon whether there is "a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." Basic, 485 U.S. at 231-32 (1988) (quoting TSC Indus., Inc. v. Northway, Inc., 426 U.S. 438, 449 (1976)). "A fact is to be considered material if there is a substantial likelihood that a reasonable person would consider it important in [making investment decisions]." Azrielli v. Cohen Law Offices, 21 F.3d

512, 518 (2d Cir. 1994). "Materiality is a mixed question of law and fact." Ganino v. Citizens Utils. Co., 228 F.3d 154, 162 (2d Cir. 2000) (citing TSC Indus., 426 U.S. at 450). Thus, in the context of a Fed. R. Civ. P. 12(b)(6) motion, "a complaint may not properly be dismissed . . . on the ground that the alleged misstatements or omissions are not material unless they are so obviously unimportant to a reasonable investor that reasonable minds could not differ on the question of their importance." Id. (citations omitted); accord Halperin v. Ebanker Usa.com, 295 F.3d 352, 357 (2d Cir. 2002).

There are two types of disclosure obligations. A duty may arise "expressly pursuant to an independent statute or regulation" – i.e. an affirmative legal disclosure obligation. Thesling v. Bioenvision, Inc., 374 Fed. Appx. 141, 143 (2d Cir. 2010); see also Glazer v. Formica Corp., 964 F.2d 149, 157 (2d Cir. 1992). Or, a duty may arise "as a result of the ongoing duty to avoid rendering existing statements misleading by failing to disclose material facts." Thesling, 374 Fed. Appx. at 143. When a corporation chooses to speak, it has a "duty to be both accurate and complete." Caiola v. Citibank, N.A., 295 F.3d 312, 331 (2d Cir. 2002). This "means only [revealing] such [facts], if any, that are needed so that what was revealed would not be so incomplete as to mislead." In re Bristol Myers Squibb Co. Sec. Litig., 586 F. Supp. 2d 148, 160 (S.D.N.Y.2008) (citation omitted); see also In re Morgan Stanley Info. Fund Sec. Litig., 592 F.3d 347 (2d Cir. 2010); Marsh & McLennan Cos. Sec. Litig., 501 F. Supp. 2d 452, 469 (2d Cir. 2006); In re Time Warner, 9 F.3d at 267. "[A] corporation is not required to disclose a fact merely because a reasonable investor would very much like to know that fact." In re Time Warner, 9 F.3d at 267. Nor is a corporation required to reveal all facts on a subject by revealing one fact. See In re Bristol Myers, 586 F. Supp. 2d at 160 (citation omitted). However, "even an

entirely truthful statement may provide a basis for liability." Id.; McMahan v. Wherehouse Entertainment, Inc., 900 F.2d 576, 579 (2d Cir. 1990) ("Some statements, although literally accurate, can become, through their context and manner of presentation, devices which mislead investors. For that reason, the disclosure required by the securities laws is measured not by literal truth, but by the ability of the material to accurately inform rather than mislead prospective buyers.").

2. Duty to Correct/Update: Pre-February 17, 2006 Statements

On March 9, 2005, during a conference call with investors and analysts, Plaintiffs allege that sanofi presented the results of the recently completed RIO-Europe study. FAC ¶ 46. Defendant Greene said, "I think at this point, we have looked at the database fairly closely and no concerns have arisen. And as you know, we're well along in amassing the entire [safety] database." FAC ¶ 46. Defendant Cluzel said, "On suicide, in fact, we have no signal. And if we have one signal, it is in placebo. So, no problem." FAC ¶ 46. Plaintiffs allege in their opposition memorandum to Defendants' motion to dismiss – but not in the FAC – that these statements became false and misleading when sanofi received the FDA's approvable letter on February 17, 2006. Plaintiffs contend that sanofi had a duty to correct, retract or otherwise update its prior statements about safety and suicidality but failed to ever do so.

"[I]t is axiomatic that the Complaint cannot be amended by the briefs in opposition to a motion to dismiss." Kosovich v. Metro Homes, LLC, 2009 U.S. Dist. LEXIS 121390, at *15 n.6 (S.D.N.Y. Dec. 29, 2009) (quoting O'Brien v. Nat'l Prop. Analysts Partners, 719 F. Supp. 222, 229 (S.D.N.Y. 1989)); Islam v. Goord, 2006 U.S. Dist. LEXIS 71853, at *2 n.2 (S.D.N.Y. Sept. 29, 2006) (collecting cases); Fadem v. Ford Motor Co., 352 F. Supp. 2d 501, 516 (S.D.N.Y.

2005) ("It is long-standing precedent in this circuit that parties cannot amend their pleadings through issues raised solely in their briefs.") (collecting cases). Nevertheless, even considering the newest set of allegations on the merits, neither of the March 2005 statements are actionable.

The duty to correct, contrary to how Plaintiffs have characterized sanofi's alleged disclosure obligation, is distinct from the duty to update. "The duty to correct applies when a company makes a historical statement that at the time made, the company believed to be true, but as revealed by subsequently discovered information actually was not." Kowal v. IBM (In re IBM Corporate Sec. Litig.), 163 F.3d 102, 109 (2d Cir. 1998) (citation omitted). It arises "if and when a speaker learns that a prior statement was misleading when made." Id. Alternatively, "[a] duty to update may exist when a statement, reasonable at the time it is made, becomes misleading because of a subsequent event." Id. at 110. It, however, is not without limits. It does not extend to: (1) "vague statements of optimism or expressions of opinion"; (2) statements that are "not forward looking and do[] not contain some factual representation that remains 'alive' in the minds of investors as a continuing representation"; or (3) statements that are not material. Id. (citations omitted).

Plaintiffs have pled insufficient facts to establish that Defendants had any disclosure obligation with respect to the March 2005 statements. The March 2005 statements cannot form the basis for a duty to correct. Plaintiffs offer no factual allegations demonstrating that the statements at issue were false *at the time that they were made*. Here, it would require that sanofi had information conveying suicidality as a "signal" or a "concern" in March 2005 – not, as Plaintiffs allege, that such information was obtained by sanofi *after the statement was made* and

thereby now invalidates the prior statements.[8] The March 2005 statements also cannot form the basis for a duty to update. The statements are not forward-looking. Furthermore, the broader context of discussing the results of a recent clinical trial, as well as the limiting language used by both Defendants, would have led a reasonable investor to understand that sanofi was conveying only the currently available safety information, rather than projecting or predicting the overall safety profile of rimonabant. Thus neither of the March 2005 statements as alleged are actionable as fraudulent misrepresentations.

3. Duty to Disclose

The remainder of the FAC identifies omissions by sanofi during the Class Period when sanofi affirmatively spoke about the FDA approval process and rimonabant's safety profile. Plaintiffs allege that sanofi publicly touted rimonabant and released only good news about rimonabant. Plaintiffs contend that, as a consequence, sanofi's statements misled investors regarding the commercial viability of rimonabant by – namely, "leading investors to believe that there had been no material change to the likelihood of FDA approval," and that "everything was going fine with the FDA review process," by withholding bad news such as information about the FDA's concerns and the risk of suicidality. FAC ¶ 9, 12; Oral Argument Transcript, at 47. Plaintiffs argue that these disclosures were required, not by an affirmative legal obligation, but rather by the duty to be complete and accurate when making public statements.

Here, Defendants are not entitled to dismissal of the FAC on the basis that they lacked a

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[8] The strongest allegations – namely, sanofi's production of records of several additional cases of suicidal ideation and the FDA's requirement that sanofi obtain a formal assessment of a possible link between rimonabant and suicidality – identified by Plaintiffs refer to events that occurred after March 9, 2005.

duty to disclose the suicidality information.[9] Rather, based upon the FAC, sanofi is a corporation that was regularly commenting about a pending drug application and Plaintiffs target the misleading information conveyed by those statements. Sanofi had an unwaivable duty to be both accurate and complete when it spoke to investors. Regardless of whether In re Carter-Wallace, Inc. Sec. Litig. or its progeny imposed an affirmative disclosure obligation on sanofi during the Class Period, the absence of an affirmative obligation does not shield a drug corporation from disclosure obligations that may be imposed by other independent grounds. 150 F.3d 153, 157 (2d Cir. 1998) (Carter-Wallace I); cf. Caiola, 295 F.3d at 331 ("[T]he lack of an independent duty is not . . . a defense to . . . liability because upon choosing to speak, one must

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[9] Carter-Wallace I provided that "[d]rug companies need not disclose isolated reports of illness suffered by users of their drugs until those reports provide statistically significant evidence that the ill effects may be caused by – rather than randomly associated with--use of the drugs and are sufficiently serious and frequent to affect future earnings." See also In re Carter-Wallace Sec. Litig. (Carter-Wallace II), 220 F.3d 36, 41 (2d Cir. 2000) ("Carter-Wallace had no sound reason to doubt the commercial viability of Felbatol or the value of its inventory until the reports of Felbatol-associated deaths became statistically significant."). However, the Supreme Court recently rejected the bright-line rule expressed in Carter-Wallace I by holding that the mere absence of statistically significant evidence does not demonstrate a lack of materiality:

> Application of Basic's "total mix" standard does not mean that pharmaceutical manufacturers must disclose all reports of adverse events. . . . The fact that a user of a drug has suffered an adverse event, standing alone, does not mean that the drug caused that event. The question remains whether a reasonable investor would have viewed the nondisclosed information as having significantly altered the "total mix" of information made available. . . . [T]he mere existence of reports of adverse events -- which says nothing in and of itself about whether the drug is causing the adverse events -- will not satisfy this standard. *Something more is needed, but that something more is not limited to statistical significance and can come from "the source, content, and context of the reports.* This contextual inquiry may reveal in some cases that reasonable investors would have viewed reports of adverse events as material even though the reports did not provide statistically significant evidence of a causal link.

See Matrixx Initiatives, Inc. v. Siracusano, 2011 U.S. LEXIS 2416, at *29-30 (U.S. Mar. 22, 2011) (internal citations and quotation marks omitted; emphasis added). Defendants' argument is thus unavailing as to both whether an affirmative duty to disclose existed and whether its alleged omissions were material.

speak truthfully and accurately."). Defendants have not identified any case law or statutes or regulations that suggests otherwise. Sanofi may not engage in affirmative conduct that misleads investors under any circumstances.

The issue at the pleading stage is whether the FAC contains sufficient factual allegations to establish that sanofi's statements were misleading (i.e. duty to disclose) in light of the omission of material facts (i.e. materiality). The Second Circuit has "drawn a distinction between concepts of a duty to disclose and materiality"; however, where the duty to disclose arises from a need to avoid false or misleading statements "the inquiries as to duty and materiality coalesce." In re Time Warner, 9 F.3d at 267 (citing Glazer v. Formica Corp., 964 F.2d 149, 157 (2d Cir. 1992)). A plaintiff need only demonstrate the materiality of the omitted facts because "[i]f a reasonable investor would so regard the omitted fact [as material], it is difficult to imagine a circumstance where the prior statement would not be rendered misleading in the absence of the disclosure." Id. at 267-68. "Whether [the omitted fact] constitutes material information, and whether nondisclosure of the [omitted fact] renders the original disclosure misleading, remain questions for the trier of fact, and may be resolved by summary judgment when there is no disputed issue of material fact." Id. at 268.

a. Statements Made After February 17, 2006, and Before October 26, 2006

The FAC identifies three statements made after February 17, 2006, the date on which sanofi received the FDA approvable letter, and before October 27, 2006, the date on which sanofi submitted the results of Dr. Posner's independent, formal assessment to the FDA.[10] Each

[10] The summary chart attached to Plaintiffs' December 20, 2010, post-oral argument submission identifies three statements during the time period in question but does not list the

of these statements are alleged to be "false and misleading" because of the following omitted facts: (1) the FDA's concerns regarding the relationship between rimonabant and suicidality[11]; and (2) the FDA's request for an independent formal assessment of the risk of suicidality.[12]

One statement alleged during this time period constitutes an actionable omission. On February 24, 2006, Plaintiffs allege that sanofi held a fourth quarter 2005 earnings conference call for investors and analysts. FAC ¶ 50. Sanofi allegedly made a presentation that emphasized the enormous market potential for rimonabant in the United States and confirmed a third quarter or fourth quarter launch date. FAC ¶ 50. Sanofi, through Defendant Le Fur, discussed the February 17, 2006 FDA letter regarding rimonabant, stating:

> So as you know, in the non-approvable letter that we received on Rimonabant, the FDA asked us to perform an additional clinical study in smoking cessation. But ***in the approvable letter, no additional trial in obesity has been requested by the agency*** and we will meet the FDA in the coming weeks to address all remaining issues.

FAC ¶ 51.

An investor could have understood this statement to mean that, with respect to rimonabant as an obesity drug, the FDA had made no other requests and/or that the FDA

August 2, 2006 statement alleged in paragraph 58 of the FAC.

[11] "After submission of the rimonabant NDA in April 2005, the FDA had requested and Sanofi had produced additional patient records that showed a 'signal' or possible causal relationship between rimonabant and suicidality. Based on that production of suicidality data and as a result of the FDA's concerns about the association between rimonabant and increased frequencies of suicidality, in February 2006 the agency required defendants to reassess the data from the clinical trials to investigate for other cases of suicidality." FAC ¶¶ 52(a), 59(a).

[12] "The FDA required defendants to obtain an independent, formal assessment of the risk of suicidality from Dr. Posner's group at Columbia University in order to investigate the signal for suicidality detected during review of the NDA." FAC ¶¶ 52(b), 59(b).

approval process was on track without any major concerns. This statement specifically addresses the content of the February 17, 2006 FDA letter, and disclosing the omitted facts may have provided a more complete picture of rimonabant's approval status, and thus significantly contributed to the total mix of information available to investors. Plaintiffs' factual allegations are sufficient to establish that the omitted facts were material and thereby that sanofi may have come under a duty to disclose one or both of the omitted facts.

The remaining statements during this time period are not actionable as alleged. On March 22, 2006, during a conference call for analysts and investors discussing fiscal year 2005, Plaintiffs allege that sanofi again made its February 24, 2006 presentation, but that an unidentified sanofi representative stated, "You know everything concerning rimonabant." FAC ¶ 55.[13] This statement constitutes mere puffery – i.e. an "exaggerated or general statement[] that make[s] no specific claims on which [reasonable persons] can rely." Pelman v. McDonald's Corp., 237 F. Supp. 2d 512, 528 n.14 (S.D.N.Y. 2003). No reasonable investor could have been led by this statement to believe that sanofi had publicly disclosed all available information regarding rimonabant.[14] A reasonable investor may have expected, as Plaintiffs contend, that they were aware of the material facts about rimonabant, but such desire to know did not impose a duty to disclose upon sanofi.[15] Even the mere fact that Plaintiffs can identify information not known by

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[13] "***You know everything concerning rimonabant.*** I can just add that we are currently working with the FDA concerning rimonabant, but I'm sorry to say that but you're pretty sure of what I said that I will not comment anymore about rimonabant." FAC ¶ 55.

[14] Plaintiffs admit this conclusion: "Standing alone, an assertion that 'you know everything' could be passed off as unactionable hyperbole and, of course, investors did not expect to know 'everything' about the drug." Pls. Mem., at 12.

[15] The omission of facts that may be material or significant by hindsight does not render their omission at a prior time misleading. This Court must engage in a statement-by-statement

investors does not render this statement materially false, absent a demonstration that such information should have been known pursuant to some duty to disclose. Thus, this statement constitutes puffery and is not actionable as a matter of law. See Novak v. Kasaaks, 216 F.3d 300, 315 (2d Cir. 2000) (material facts do not include "statements containing simple economic projections, expressions of optimism, and other puffery"); accord Rombach v. Chang, 355 F.3d 164, 174 (2d Cir. 2004) ("expressions of puffery and corporate optimism do not give rise to securities violations").

On May 5, 2006, during a conference call for investors and analysts discussing first quarter 2006 earnings, Plaintiffs allege that sanofi responded to questions regarding the launch date for rimonabant in the United States. FAC ¶ 55. Defendant Spek stated that "[W]e are still planning and we continue to plan for a launch also in the U.S. in the second half of 2006." FAC ¶ 56.[16] This statement expresses general corporate optimism regarding rimonabant and thus is

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analysis to make such a determination at the pleading stage.

[16] The entire exchange reproduced in the FAC ¶ 56 is as follows:

[PRUDENTIAL SECURITIES ANALYST]: Thank you. A few questions. ***On Acomplia, are you guys still guiding for a second half [2006] launch in the U.S.?***

* * *

[SPEK]: Tim, thank you for your questions. On Acomplia, I think we can say absolutely nothing else. **We remain confident and prepared to launch Acomplia during the second half of 2005 - in 2006, excuse me.** We remain in a permanent exchange with the FDA.

* * *

[MERRILL LYNCH ANALYST]: Hi, good morning. Thanks for taking my questions. Firstly, on Accomplia, can you just confirm that you have had a meeting with the FDA post your approvable letter and that ***your second half launch guidance is based on the discussions you've had from that meeting?***

* * *

[SPEK]: Then, on the ongoing conversation with the FDA, I cannot confirm to you that we had one meeting, as your question has been posed. I said earlier that we are in a permanent dialogue with the agency and I have nothing to add to this. But as also previously stated, ***yes, we are still planning and we continue to plan for a launch also in the U.S. in the second half of 2006.***

not actionable as a matter of law.[17] See Rombach, 355 F.3d at 174; Novak, 216 F.3d at 315.

Plaintiffs have failed to plead sufficient factual allegations to demonstrate that this statement constituted something other than genuine corporate optimism. Plaintiffs never allege any facts that would demonstrate that, at the time the statement was made, Defendants were either not planning for a launch in the second half of 2006 or not planning to continue such efforts in the future. Plaintiffs have also not alleged any facts that would demonstrate that a reasonable investor could have understood this statement to convey a guarantee about the timing or success of the rimonabant launch.[18] Whether sanofi's optimism was, by hindsight, unwarranted "do[es] not give rise to securities violations" because "[u]p to a point, companies must be permitted to operate with a hopeful outlook." Rombach, 355 F.3d at 174 (citing Shields v. Citytrust Bancorp, Inc., 25 F.3d 1124, 1129-30 (2d Cir. 1994)).

b. Statements Made After October 26, 2006, and Before June 17, 2007

The FAC identifies five statements made after October 26, 2006, the date on which sanofi submitted the results of Dr. Posner's independent, formal assessment to the FDA, and before June 17, 2007, the date on which the FDA disclosed the suicidality information on rimonabant.[19] Each statement is alleged to be "false and misleading" because of the omission of various facts.

Three statements identified in the FAC involve sanofi's interpretation of the results of

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[17] The PSLRA safe harbor is inapplicable because the statement "has both a forward-looking aspect and an aspect that encompasses a representation of present fact." In re Nortel Networks Corp. Sec. Litig., 238 F. Supp. 2d 613, 629 (S.D.N.Y. 2003).

[18] The FAC lacks any factual allegations regarding the falsity of sanofi's statement at the time it was made, precluding the duty to correct. The FAC also lacks any fails to establish a duty to update because sanofi made a general statement of optimism.

[19] The summary chart attached to Plaintiffs' December 20, 2010, post-oral argument submission identifies five statements during the time period in question.

rimonabant clinical trials. On October 27, 2006, sanofi's press release announced the publication of the RIO-Diabetes Study, stating that "results of [RIO Diabetes] were consistent with the data from the entire RIO [rimobrant] clinical trial programme . . . . Side effects were mainly mild, transient, [and] self-limiting . . . ." FAC ¶ 63. On November 9, 2006, during a conference call hosted by Credit-Suisse, Plaintiffs allege that Defendant Cluzel and another sanofi representative made a presentation on the market for rimonabant. FAC ¶ 69. One of the slides stated that: "Long term exposure did not identify new or increased risks." FAC ¶ 69. Finally, on December 5, 2006, during a conference call for analysts and investors, Plaintiffs allege that sanofi presented the results of the SERENADE clinical trial. Defendant Green stated that , "[T]he safety profile was consistent with what we've seen in the past, which we found reassuring." FAC ¶ 72.

Plaintiffs challenge sanofi's publicly stated interpretations of the results of various clinical studies, statements which are essentially no different than opinions.[20] To properly plead that such statements were materially misleading, Plaintiffs must "allege 'with particularity' 'provable facts' to demonstrate that the statement of opinion is both objectively and subjectively false." Bond Opportunity Fund v. Unilab Corp., 2003 U.S. Dist. LEXIS 7838, at *15 (S.D.N.Y. May 9, 2003) (citing Va. Bankshares, Inc. v. Sandberg, 501 U.S. 1083, 1094 (1991)), aff'd, 87 Fed. Appx. 772 (2d Cir. Feb. 10, 2004) (summary order); see also Podany v. Robertson Stephens, Inc., 318 F. Supp. 2d 146, 154 (S.D.N.Y. 2004) ("[A] material misstatement of opinion is by its nature a false statement, not about the objective world, but about the defendant's own belief. Essentially, proving the falsity of the statement . . . is the same as proving scienter,

[20] Reasonable persons may disagree over how to analyze data and interpret results, and neither lends itself to objective conclusions.

since the statement (unlike a statement of fact) cannot be false at all unless the speaker is knowingly misstating his truly held opinion."). That is, Plaintiffs "must show both that the [Defendants] did not actually hold the belief or opinion stated, *and* that the opinion stated was in fact incorrect." Id. (emphasis in original; citations omitted).

Here, the FAC lacks sufficient factual allegations to satisfy either requirement. Plaintiffs cannot premise a fraud claim upon a mere disagreement with how sanofi chose to interpret the results.[21] Plaintiffs never allege any facts, even on information and belief, demonstrating that sanofi's publicly expressed opinions were different than or contradicted by the true opinions of sanofi or any of the Individual Defendants. There is no basis to conclude that sanofi characterized the results of the clinical trial or rimonabant's safety profile in a manner inconsistent with what they believed to be the truth. Plaintiffs have also failed to offer any specific allegations of contemporaneous institutional knowledge that could be ascribed to sanofi that rendered the publicly expressed opinions false. None of the omitted facts identified for each of the statements raise a conflict between sanofi's knowledge and its publicly expressed opinion.[22] Therefore, none of the statements of opinion are actionable.

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[21] See In re Salomon Analyst AT&T Litig., 350 F. Supp. 2d 455, 466 (S.D.N.Y. 2004) ("It is not sufficient for these purposes to allege that an opinion was unreasonable, irrational, excessively optimistic, not borne out by subsequent events, or any other characterization that relies on hindsight or falls short of an identifiable gap between the opinion publicly expressed and the opinion truly held."); Podany v. Robertson Stephens, Inc., 318 F. Supp. 2d 146, 154 (S.D.N.Y. 2004) ("It is not sufficient to allege, as plaintiffs have done in both cases addressed here, that it would have been possible to reach a different opinion than that reached by defendant based on information available to defendant at the time, or even that the defendant's opinion was unreasonable. A securities fraud action may not rest on allegations that amount to second-guesses of defendants' opinions about the future value of issuers' stock -second-guesses made all too easy with the benefit of hindsight.").

[22] With respect to the October 27, 2006 statement and the December 5, 2006 statement, the omitted facts do not raise a conflict. FAC ¶¶ 59, 64, 74. The FDA's concerns and requests,

One statement identified in the FAC pertains to sanofi's submission of data. On October 31, 2006, during a conference call for investors and analysts, an analyst asked, **"Was additional data submitted?** Was additional data not submitted?" FAC ¶ 66. Sanofi, through Defendant Spek, responded, "We have received an approvable letter and usually, and also in this case, an approvable letter contains questions. We have answered to those questions ***and as the approvable letter did not ask for new additional clinical trials, consequently it is easier for me to say that we have not submitted new data in this respect.***" FAC ¶ 66. Plaintiffs allege that the statement was "false and misleading" because of the following omitted facts: (a) "the FDA had requested and sanofi had produced additional patient records that showed a 'signal' or possible causal relationship between rimonabant and suicidality"; (b) the FDA required defendants to reassess the data from the clinical trials to investigate for other cases of suicidality and Dr. Kelly Posner commenced an independent, formal assessment; (c) Defendants "submitted new data to the FDA, specifically the results of Dr. Posner's suicidality assessment"; (d) "the independent assessment . . . showed a statistically significant link between rimonabant and suicidality." FAC ¶ 67.

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as well as the results of Dr. Posner's assessment, are wholly irrelevant to the accuracy of sanofi's specific characterizations of the results of either clinical study. The fact that suicidality is more prevalent amongst the rimonabant group than the placebo group (i.e. a result from the RIO study) does not address whether the overall safety results of the RIO study were consistent across rimonabant trials. Plaintiffs do not offer, for example, factual allegations of clinical trials with substantially different findings from the RIO study or side effects in the RIO study that were both serious and pervasive. Similarly, the fact that sanofi submitted results from an independent, formal assessment separate from the SERENADE study does not address whether the overall safety results of the SERENADE study were consistent with what was observed in the past. Absent additional allegations, neither statement has been demonstrated as false. With respect to the November 9, 2006 statement, the same is also true. The omitted facts, FAC ¶ 70, suggest that Plaintiffs could have reached a different conclusion but they do not demonstrate that sanofi's statement are false.

This statement is actionable because Plaintiffs have alleged sufficient facts to establish that Spek's response could have been misleading to a reasonable investor. There were two truthful but complete responses to the analysts's question.[23] Sanofi could have declined to answer – that is, make no comment on additional data submissions or the content of the FDA approvable letter. Or Defendants could have answered "yes." Defendants, as identified by the omitted facts, had submitted additional data. Thus, in choosing to comment on additional data submissions, Defendants could not provide a truthful and complete response without conveying to the public that additional data had been requested and submitted. The mere fact that an analyst asked the question indicates that it may not have been obvious to a reasonable investor that sanofi was submitting new data to the FDA. By answering "no," Spek's response could have led a reasonable investor to believe that sanofi had not submitted new data on some issue that concerned the FDA. This is plausible even with Spek's "in this respect" clarification. The reality is that the alleged omitted facts are sufficiently related to this statement that disclosing such information may have significantly contributed to the total mix of information available to investors. Plaintiffs' factual allegations are sufficient to establish that the omitted facts were material and thereby that sanofi may have come under a duty to disclose some or all of the omitted facts. Accordingly, this statement is actionable.

The final statement identified in the FAC was made in a press release entitled "Rimonabant US: Update" on February 12, 2007. FAC ¶ 73. Sanofi stated that, "***The Group also announced the submission of the SERENADE clinical study report today in the***

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[23] As the Court noted at Oral Argument on the pending motion, it is clear that the reasonable way to interpret the analyst's question is "have you been asked to submit new data on some issue that the FDA had some concern about." Oral Argument Transcript, at 32.

rimonabant NDA submitted to the FDA." FAC ¶ 73. This statement is not actionable. This statement conveys a clear and accurate historical fact. No reasonable investor would have construed this statement to make any representation regarding any of the omitted facts – that is, the FDA's concern about suicidality, the FDA's request for an independent formal assessment of the risk of suicidality, the results of Dr. Posner's study that were submitted to the FDA, or sanofi's submission of Dr. Posner's results. See FAC ¶ 74. No reasonable investor could have been mislead to believe something in contradiction to the omitted facts. The statement conveys no information about the status of the approval process, the submission of data, or the available results. The omitted facts do not even relate to the results or findings of the SERENADE clinical study. Plaintiffs cannot seize upon sanofi's use of the word "update" in the title or sanofi's cursory discussion of the completion of a specific clinical trial to require disclosure of all facts or results of interest to Plaintiffs. The omitted facts are objectively and obviously unimportant to the statement at issue. Plaintiffs have thus failed to demonstrate that this statement was misleading.

In sum, the FAC identifies two statements by sanofi that could constitute actionable omissions – (1) "[I]n the approvable letter, no additional trial in obesity has been requested by the agency," FAC ¶ 51; and (2) "[W]e have not submitted new data," FAC ¶ 66.

B. Scienter

1. Legal Standard

To state a claim under Section 10(b) and Rule 10b-5, a plaintiff must plead, inter alia, that each defendant "acted with scienter, a mental state embracing intent to deceive, manipulate, or defraud." Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 319 (2007) (citing Ernst

& Ernst v. Hochfelder, 425 U.S. 185, 193-194 (1976)). On a motion to dismiss, the court must "consider the complaint in its entirety," inquiring "whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard."[24] Id. at 323. "[A] court must consider plausible, nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff." Id. at 324. "A complaint will survive . . . only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." Id. A plaintiff can satisfy this requirement by "alleging [particularized] facts (1) showing that the defendant had both motive and opportunity to commit the fraud or (2) constituting strong circumstantial evidence of conscious misbehavior or recklessness." ATSI Commc'ns, Inc. v. Shaar Fund, Ltd., 493 F.3d 87, 99 (2d Cir. 2007); see also 15 U.S.C. § 78u-4(b)(2) (PSLRA requirement to "state with particularity facts giving rise to a strong inference that the defendant acted with the required mental state, scienter.").

2. Motive and Opportunity

Plaintiffs allege that "defendants were . . . motivated to conceal the link [between rimonabant and suicidality] in order to gain approval of outstanding drug applications by regulatory bodies other than the FDA before the truth about the drug emerged." FAC ¶ 37. Sanofi allegedly had outstanding applications with the European Commission, Mexico, Switzerland and Brazil that "were set to be, and were, acted on before the FDA Advisory

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[24] When the defendant is a corporation, "the pleaded facts must create a strong inference that someone whose intent could be imputed to the corporation acted with the requisite scienter." Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital, Inc., 531 F.3d 190, 195 (2d Cir. 2008). "In most cases, the most straightforward way to raise such an inference for a corporate defendant will be to plead it for an individual defendant." Id.

Committee had a chance to address the rimonabant safety data and disclose the link." FAC ¶ 37. Plaintiffs further allege that sanofi's "misleading statements and material omissions helped . . . sell more than €68 million worth of rimonabant outside the United States" during the class period. FAC ¶ 37.

Plaintiffs' factual allegations are insufficient, as a matter of law, to establish that sanofi had a motive to commit securities fraud. Plaintiffs have only identified generalized motives. The desire to have a drug application approved, or even approved by multiple authorities, can be ascribed to any pharmaceutical company. Similarly, the desire to maximize revenue from a product can be ascribed to any for-profit company in any industry.[25] Neither motive is "sufficiently concrete for purposes of inferring scienter." Chill v. General Elec. Co., 101 F.3d 263, 268 (2d Cir. 1996); see also ECA & Local 134, 553 F.3d at 198 ("Motives that are common to most corporate officers, such as the desire for the corporation to appear profitable and the desire to keep stock prices high to increase officer compensation, do not constitute 'motive' for purposes of this inquiry."); Novak, 216 F.3d at 307-08 (defendants must have "benefitted in some concrete and personal way from the purported fraud.").

3. Conscious Misbehavior or Recklessness

"Where motive is not apparent, it is still possible to plead scienter by identifying circumstances indicating conscious behavior by the defendant, though the strength of the

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[25] Identifying the amount of rimonabant sold during the Class Period misconstrues the requirement that "plaintiffs must assert a concrete and personal benefit to the individual defendants resulting from the fraud." Kalnit v. Eichler, 264 F.3d 131, 139 (2d Cir. 2001). Plaintiffs do not offer any factual allegations suggesting that sanofi made the allegedly material omissions in order to sell a certain amount of rimonabant. The motive underlying Plaintiffs' allegation is that sanofi desired to sell rimonabant. The fact that sanofi ultimately sold €68 million worth of rimonabant does not personalize the general motive.

circumstantial allegations must be correspondingly greater." Kalnit, 264 F.3d at 142. "Intentional misconduct is easily identified since it encompasses deliberate illegal behavior . . . ." Novak, 216 F.3d at 308. Recklessness, on the other hand, exists where the conduct is "highly unreasonable" and "represents an extreme departure from the standards of ordinary care" in light of the fact that "the danger was either known to the defendant or so obvious that the defendant must have been aware of it. Kalnit, 264 F.3d at 142 (quoting Carter-Wallace I, 220 F.3d at 39); Novak, 216 F.3d at 308. "[S]ecurities fraud claims typically have sufficed to state a claim based on recklessness when they have specifically alleged defendants' knowledge of facts or access to information contradicting their public statements." Id. (quoting Novak, 216 F.3d at 308).

The factual allegations in the FAC are sufficient to raise a strong inference that sanofi's alleged omission constituted recklessness. Plaintiffs have specifically alleged that sanofi and the individual defendants who were speakers had either knowledge of or access to the omitted facts. With respect to the February 24, 2006 statement,[26] Plaintiffs allege that the FDA sent sanofi the approvable letter expressing concern over the risk of suicidality and requesting a formal, independent assessment on suicidality on February 17, 2006. FAC ¶ 7. Plaintiffs also allege that Defendant Le Fur, the speaker who addressed the contents of the February 17, 2006 approvable letter, served as Senior Executive Vice President of Scientific and Medical Affairs, and was responsible for monitoring and reporting to investors and the market on the status of sanofi's pharmaceutical pipeline and new drug applications. FAC ¶¶ 22, 31. Plaintiffs also generally allege that the Individual Defendants "did influence and control . . . the decision-making of the Company, including the content and dissemination of the various statements which [P]laintiffs

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[26] For the omitted facts at issue, see notes 11 and 12.

contend are false and misleading" and "participated in conference calls with investors and were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements, alleged by [P]laintiffs to be misleading." FAC ¶ 127.

With respect to the October 31, 2006 statement,[27] Plaintiffs allege that the FDA directed sanofi to obtain a formal, independent assessment of the risk of suicidality. FAC ¶ 7. Plaintiffs allege that Dr. Posner conducted the assessment, FAC ¶ 8, and that her results – namely, a definite, statistically significant link between rimonabant and suicidality, FAC ¶ 10 – placed sanofi's FDA application in "extreme peril." FAC ¶ 11. Plaintiffs allege that, on October 26, 2006, sanofi had submitted the assessment results to the FDA. FAC ¶¶ 10, 11. Furthermore, in addition to the general allegations recited above, Plaintiffs allege that Defendant Spek, the speaker who addressed whether sanofi had submitted additional data to the FDA, served as Executive Vice President of Pharmaceutical Operations, and was responsible for monitoring and reporting to investors and the market on the status of sanofi's pharmaceutical pipeline and new drug applications. FAC ¶¶ 24, 31.[28] These allegations are sufficient to raise a strong inference of scienter.

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[27] For the omitted facts at issue, see pg. 21.

[28] Additionally, the October 31, 2006 statement presents a situation where sanofi was directly nonresponsive to a question. The analyst asked sanofi a question about the submission of new data. Sanofi answered with information about additional clinical trials. This suggests that sanofi may have been avoiding the question and thus by implication avoiding the disclosure of the allegedly material omitted facts. At the present stage, the circumstances surrounding this actionable statement are sufficient to raise a strong inference of scienter by sanofi and Defendant Spek.

SECTION 20(a) CONTROL PERSON LIABILITY CLAIM

"To establish a prima facie case of control person liability, a plaintiff must show (1) a primary violation by the controlled person, (2) control of the primary violator by the defendant, and (3) that the defendant was, in some meaningful sense, a culpable participant in the controlled person's fraud." See ATSI Communs, 493 F.3d at 108; SEC v. First Jersey Sec., Inc., 101 F.3d 1450, 1472 (2d Cir. 1996). Here, Defendants challenge solely the pleading of the third element.

Plaintiffs' factual allegations are sufficient to sustain a section 20(a) claim against Defendants Le Fur and Spek. See Lapin v. Goldman Sachs Group, Inc., 506 F. Supp. 2d 221, 246 (S.D.N.Y. 2006) ("[I]n order to withstand a motion to dismiss, a section 20(a) claim must allege, at a minimum, particularized facts of the controlling person's conscious misbehavior or recklessness."); see, e.g., In re CIT Group Inc. Sec. Litig., 2010 U.S. Dist. LEXIS 57467, at *15 (S.D.N.Y. June 10, 2010). Each of these Individual Defendants was a decision-making official who made an allegedly fraudulent statement about rimonabant. Each also had, as previously discussed, knowledge of or access to the omitted facts that allegedly rendered his statements misleading, and thus for the purposes of the pleading stage engaged in conduct that may constitute recklessness.

Plaintiffs' factual allegations, however, are insufficient with respect to the other individually named Defendants – Dehecq, Cluzel, Lehner, Greene, and Leroy. None of these Individual Defendants are alleged to have made either of the statements that constitute actionable omissions. Plaintiffs fail to allege any particularized facts indicating that any of these Individual Defendants had "actual control" over the statements that were made, In re Alstom, 406 F. Supp. 2d at 487 (citations omitted), or otherwise played some discernible role in the making of those

statements. Merely generally alleging that these Individual Defendants were decision-making officials or had access to material information is inadequate circumstantial evidence that does not indicate involvement in perpetrating the fraud. Plaintiffs have thus failed to establish culpable participation as to any of those Individual Defendants. Therefore, Plaintiffs have failed to state a Section 20(a) claim against them.

CONCLUSION

Defendants sanofi, Le Fur, and Spek's motion to dismiss is DENIED. Plaintiffs' Section 20(a) Claim is DISMISSED as to Individual Defendants Jean-Francois Dehecq, Marc Cluzel, Jean-Pierre Lehner, Douglas A. Greene, and Jean-Claude Leroy.

Plaintiffs' motion for the issuance of a letter of request pursuant to the Hague Convention is DENIED without prejudice to renew after the parties engage in discovery.[29]

Dated: New York, New York
March 30, 2011

SO ORDERED:

George B. Daniels

GEORGE B. DANIELS
United States District Judge

[29] First, Plaintiffs effectively withdrew their original motion by no longer seeking relief pursuant to the Hague Convention, when it requested that this Court issue a revised letter of request to the British High Court based upon English Law. Second, Plaintiffs amended their request in a significant manner after the briefing period closed, and Defendants have not been afforded a full and fair opportunity to be heard. Finally, discovery is currently stayed pursuant to section 4(b)(3)(B) of the PSLRA, and Plaintiffs have not yet attempted to obtain the requested documents from the Defendants.